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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 10/777,802 | 02/12/2004 | Sheng-Ping (Samuel) Zhong | 03-235 | 5369 |
| 27774 7590 12/02/2008 MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090 | | | | |
| EXAMINER | | | | |
| AHMED, HASAN SYED | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1615 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 12/02/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,802

Applicant(s)

ZHONG, SHENG-PING (SAMUEL)

Examiner

HASAN S. AHMED

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4-16, 20, 24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 21-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

- Receipt is acknowledged of applicant's amendment and response, which were filed on 12 September 2008.
- The 35 USC 112 rejection of the previous Office action is withdrawn in view of the amendment.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 September 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 17-19, 21-23, and 25 remain rejected under 35 U.S.C. 102(a) as being anticipated by WO 2003/026532 ("Weber").

Weber discloses a medical article comprising a release region (*see* page 2, lines 22-28), further comprising:

- the polymeric carrier comprising a first polymer of instant claim 1 (*see* page 8, lines 5-15);
- the drug loaded nanoparticles dispersed within the polymeric carrier of instant claim 1 (*see* page 11, lines 14-16);
- the layered silicate material (phyllosilicate) of instant claim 1 (*see* page 9, line 4);
- the hydrophilic therapeutic agent of instant claim 2 (*see* page 11, line 17 – page 12, line 6; *e.g.* acetylsalicylic acid);
- the hydrophobic polymer of instant claim 2 (*see* page 8, lines 5-15; *e.g.* polyolefin block copolymer);
- the disposal over at least a portion of the medical article substrate of instant claim 17 (*see* figure 1);
- the coronary or peripheral vasculature implantable or insertable medical device of instant claim 19 (*see* page 20, lines 16-21);
- the catheter of instant claim 21 (*see* page 20, line 19);
- the antithrombotic agent of instant claim 22 (*see* page 11, line 18);
- the smectite silicate material of instant claim 23 (*see* page 9, line 4); and
- the method of instant claim 25 (*see* page 6, lines 3-15).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Weber in view of U.S. Application No. 2005/0149175 ("Hunter").

Weber teaches a medical article comprising a release region (see above). The disclosed article comprises the polyolefin-polyvinylaromatic block copolymer of instant claim 3 (see page 8, lines 5-15).

Weber explains that the disclosed invention, "...advantageously provides the opportunity to provide a variation in one or more properties within one or more dimensions of the inventive device than can be achieved in medical devices not comprising nanomaterials." See page 18, lines 25-27.

Weber differs from the instant application in that it does not teach halofuginone as a therapeutic agent. However, use of halofuginone as a therapeutic agent in vascular medical devices was well known in the art at the time the instant application was filed, as evinced by Hunter (see paragraph 0415).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a vascular medical device comprising a release region, further comprising a polymeric carrier and nanoparticles comprising halofuginone, as taught by Weber in view of Hunter. One of ordinary skill in the art at the time the

invention was made would have been motivated to make such a composition because it provides more flexibility in properties than medical devices not comprising nanomaterials, as explained by Weber.

* * * * *

Response to Arguments

Applicant's arguments filed on 12 September 2008 have been fully considered but they are not persuasive.

35 USC 102(a)

Applicant argues that, "...there is no instruction or enabling disclosure in Weber for incorporating a therapeutic agent into a layered silicate material to create the claimed nanoparticle structure..." See remarks, pages 7-8.

Examiner respectfully submits that like applicant, Weber discloses drug loaded nanoparticles (see page 11, lines 14-16). Like applicant, Weber's nanoparticles may comprise layered silicate (phyllosilicate) material (see page 9, line 4). Like applicant, Weber discloses a hydrophilic therapeutic agent (see page 11, line 17 – page 12, line 6) and a hydrophobic polymer (see page 8, lines 5-15). Like applicant, Weber discloses layered silicate material comprising smectite (see page 6, lines 3-15).

Since Weber uses the silicate nanoparticles made of the same material as recited in the instant application and associates those nanoparticles with the same therapeutic agents as recited in the instant application, examiner respectfully submits that Weber's therapeutic agent will inherently associate with Weber's silicate nanoparticles in the manner recited in instant claim 1 and will inherently form the depot

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of instant claim 1. As explained in the instant application (*see, e.g.*, paragraph 0033), Weber's therapeutic agent and Weber's layered silicate may both be hydrophilic or hydrophobic, causing spontaneous association of the therapeutic agent with the layered silicate in the manner recited in instant claim 1. As such, examiner respectfully submits that Weber anticipates the instant application as claimed.

* * *

35 USC 103(a)

Applicant argues that the obviousness rejection fails because Weber does not anticipate instant claim 1. See remarks, pages 8-9.

As explained above and contrary to applicant's assertion, it is examiner's position that Weber anticipates instant claim 1.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615